

Remarks

Support for New Claims 47-51

The specification supports new claims 47-49 at page 21, lines 14-21; new claim 50 at page 21, line 34 to page 22, line 3; and new claim 51 at page 22, lines 4-10.

Objection to the Specification

The Office Action objects to the specification because it contains a hyperlink on page 18. This paper amends the specification to remove the hyperlink. Please withdraw the objection.

The Rejection of Claims 42, 44, and 45 Under 35 U.S.C. § 103(a)

Claims 42, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as obvious over Nef *et al.*, *Proc. Natl. Acad. Sci. USA* 89, 8948-52, 1992 (“Nef”). Applicants respectfully traverse the rejection.

The U.S. Patent and Trademark Office bears the initial burden of establishing a *prima facie* case of obviousness. The *prima facie* case requires, *inter alia*, a showing that Nef suggests all the claim limitations: “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. 8th ed. § 2142. Nef does not meet this requirement.

Independent claim 42, as amended, recites “a preparation comprising an antibody that specifically binds to the polypeptide of SEQ ID NO:6.” The Office Action asserts that “specifically binds to” as recited in claim 42 “is recognized the art as referring to an antibody that binds to an epitope contain[ed] within a referenced molecule without binding to any molecule lacking that epitope.” Office Action at page 3, 2nd paragraph. The Office Action asserts that Nef teaches a protein which has short amino acid sequences in common with SEQ ID

NO:6, which the Office Action characterizes as “epitopes.” The Office Action contends that, because it was known to visualize proteins using antibodies, it would have been obvious to make antibodies to the protein of Nef and that these antibodies also would “specifically bind” to the protein recited in claim 42.

The Office Action does not make a *prima facie* case that claims 42, 44, and 45 are obvious. First, Nef neither teaches nor suggests any antibodies whatsoever. Nef describes a PCR-based strategy for visualizing distribution of an olfactory receptor in the mouse olfactory system. Nef does not describe antibodies or immunochemistry and does not suggest visualization of the receptor protein itself. Mere disclosure of a receptor protein and a nucleic acid-based means of visualizing its distribution does not suggest making antibodies which bind to the protein. The *prima facie* case fails for that reason alone.

Second, even if, *arguendo*, the ordinary artisan did make antibodies to Nef’s protein, these antibodies would not “specifically bind to the polypeptide of SEQ ID NO:6,” as recited in claim 42. The phrase “specifically binds” must be understood as that phrase is defined in the specification, not according to the Examiner’s perception of what is recognized in the art:

The written description must also be examined, because it is relevant to aid in the claim construction analysis, e.g., to determine if the presumption of ordinary and customary meaning is rebutted. The presumption will be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth a definition of the term different from its ordinary and customary meaning.

ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1090-91, 68 U.S.P.Q.2d 1516, 1523 (Fed. Cir. 2003) (internal references omitted). Applicants do not concede that the Examiner has correctly characterized how one skilled in the art would understand the term “specifically binds.” In any event, the specification defines specific binding between a protein and an antibody as follows:

The phrase “specifically (or selectively) binds” to an antibody or “specifically (or selectively) immunoreactive with,” when referring to a protein or peptide, refers to a binding reaction that is determinative of the presence of the protein in a heterogeneous population of proteins and other biologics. Thus, under designated immunoassay conditions, the specified antibodies bind to a particular protein at least two times the background and do not substantially bind in a significant amount to other proteins present in the sample. Specific binding to an antibody under such conditions may require an antibody that is selected for its specificity for a particular protein. For example, polyclonal antibodies raised to a particular BCA-GPCR can be selected to obtain only those polyclonal antibodies that are specifically immunoreactive with the BCA-GPCR, and not with other proteins, except for polymorphic variants, orthologs, and alleles of the BCA-GPCR. This selection may be achieved by subtracting out antibodies that cross-react with BCA-GPCR molecules. A variety of immunoassay formats may be used to select antibodies specifically immunoreactive with a particular protein. For example, solid-phase ELISA immunoassays are routinely used to select antibodies specifically immunoreactive with a protein (see, e.g., Harlow & Lane, *Antibodies, A Laboratory Manual* (1988), for a description of immunoassay formats and conditions that can be used to determine specific immunoreactivity). Typically a specific or selective reaction will be at least twice background signal or noise and more typically more than 10 to 100 times background. Antibodies that react only with a particular BCA-GPCR ortholog, e.g., from specific species such as rat, mouse, or human, can also be made as described above, by subtracting out antibodies that bind to the same BCA-GPCR from another species.

Page 22, line 14, to page 23, line 5. According to this definition, the claimed antibodies do “not substantially bind in a significant amount” to other proteins, including the protein disclosed in Nef. Thus, even if one of ordinary skill in the art were motivated to make antibodies to the protein of Nef, those antibodies would not render the claimed antibodies obvious.

Because Nef does not suggest antibodies which specifically bind to the polypeptide of SEQ ID NO:6, as recited in independent claim 42, there is no *prima facie* case that claims 42, 44, and 45 are obvious. Applications respectfully request withdrawal of the rejection.

Respectfully submitted,

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